



Industry Perspective on the Medical Device Single Audit Program (MDSAP)

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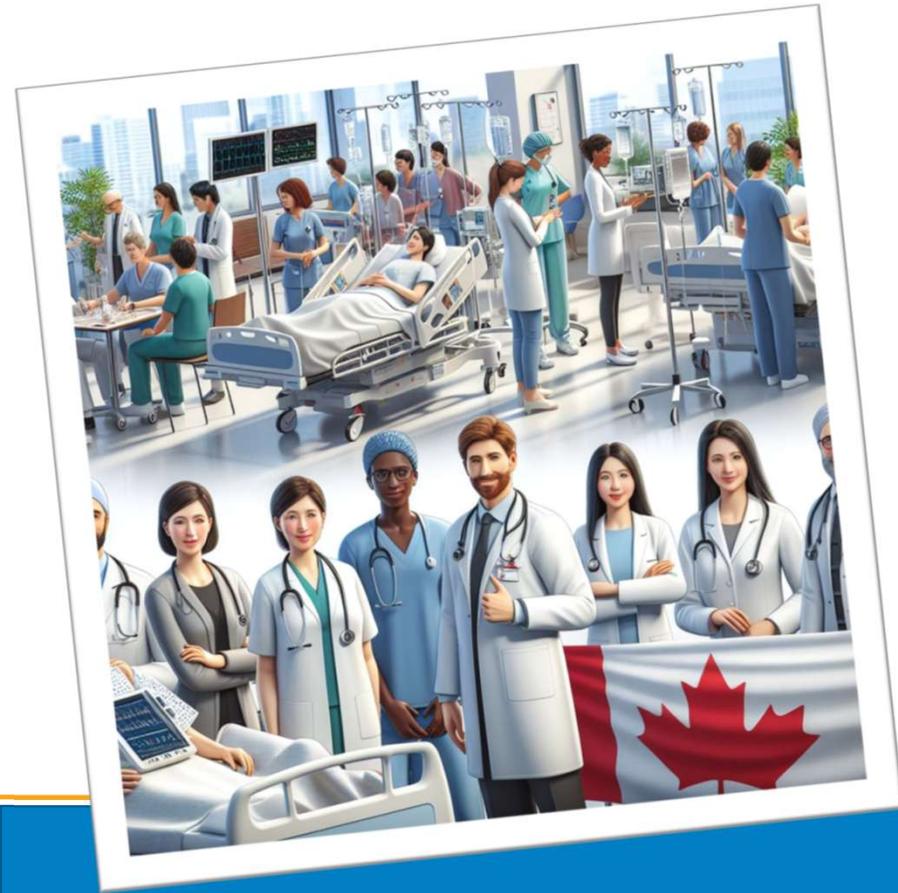
VP Regulatory, Quality and Environmental Affairs

Medtech Canada - Who we are

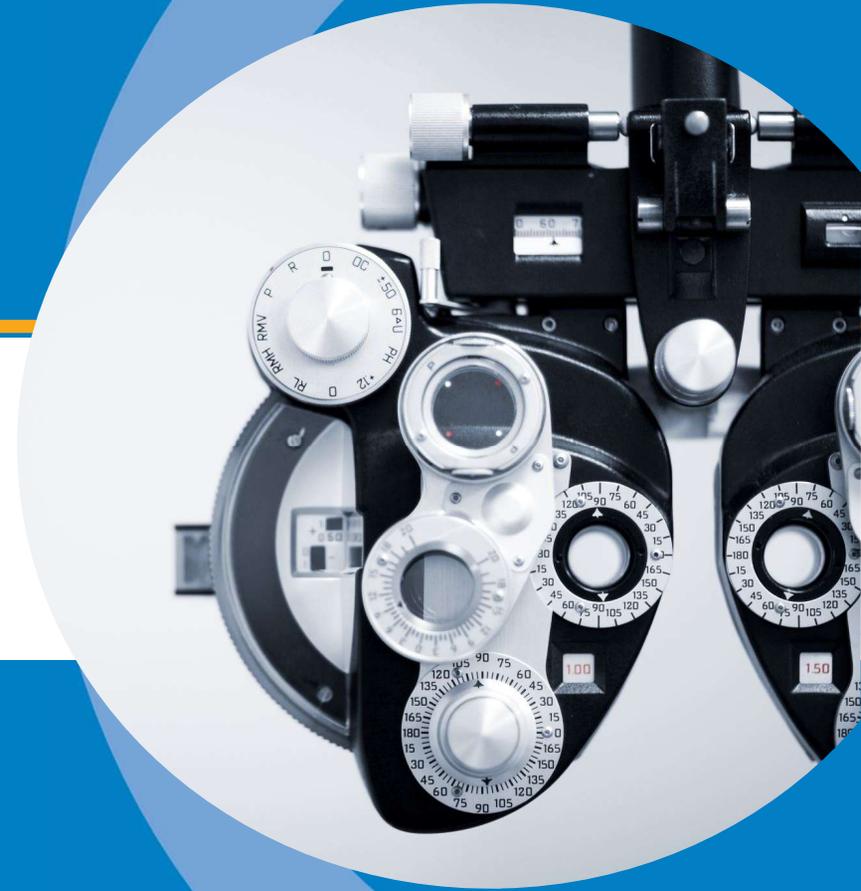
Mission: We foster a strong, dynamic medical technology sector for better health outcomes for Canadians.

Vision: For Canada to be a world leader in realizing the benefits of medical technologies.

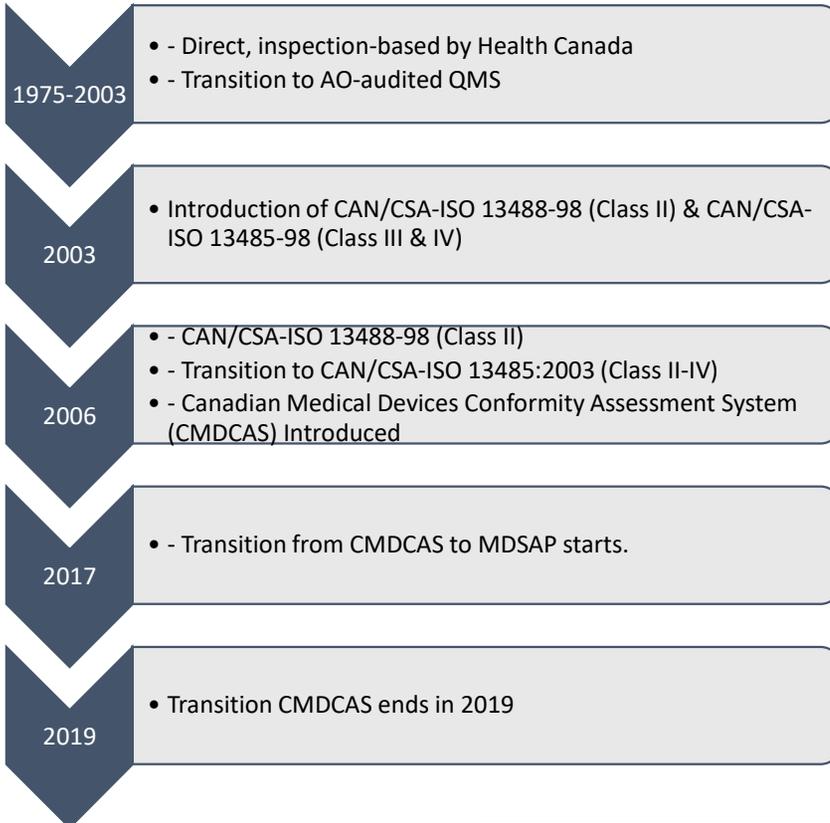
Advocacy: Promoting the industry and bringing forward key messages through active engagement and involvement with stakeholders.



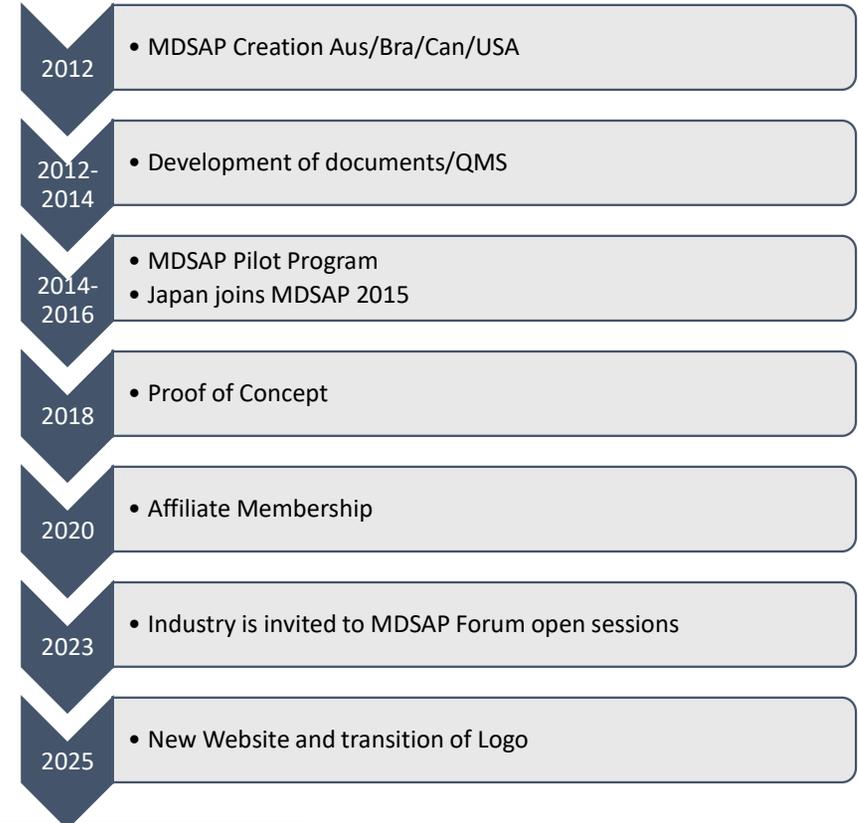
Historical Development of Medical Device Quality Systems in Canada



Canada



Canada + International



MDSAP reach and global adoption – an important aspect for Canadian Healthcare



MDSAP

Medical Device Single Audit Program

31,426

Number of MDSAP Audits
Conducted
(January 2018-May 2025)

15

Number of Auditing
Organizations able to
conduct MDSAP audits

5,722

Number of Unique
Facility IDs

82

Number of Countries where
MDSAP Audits occurred

7,357

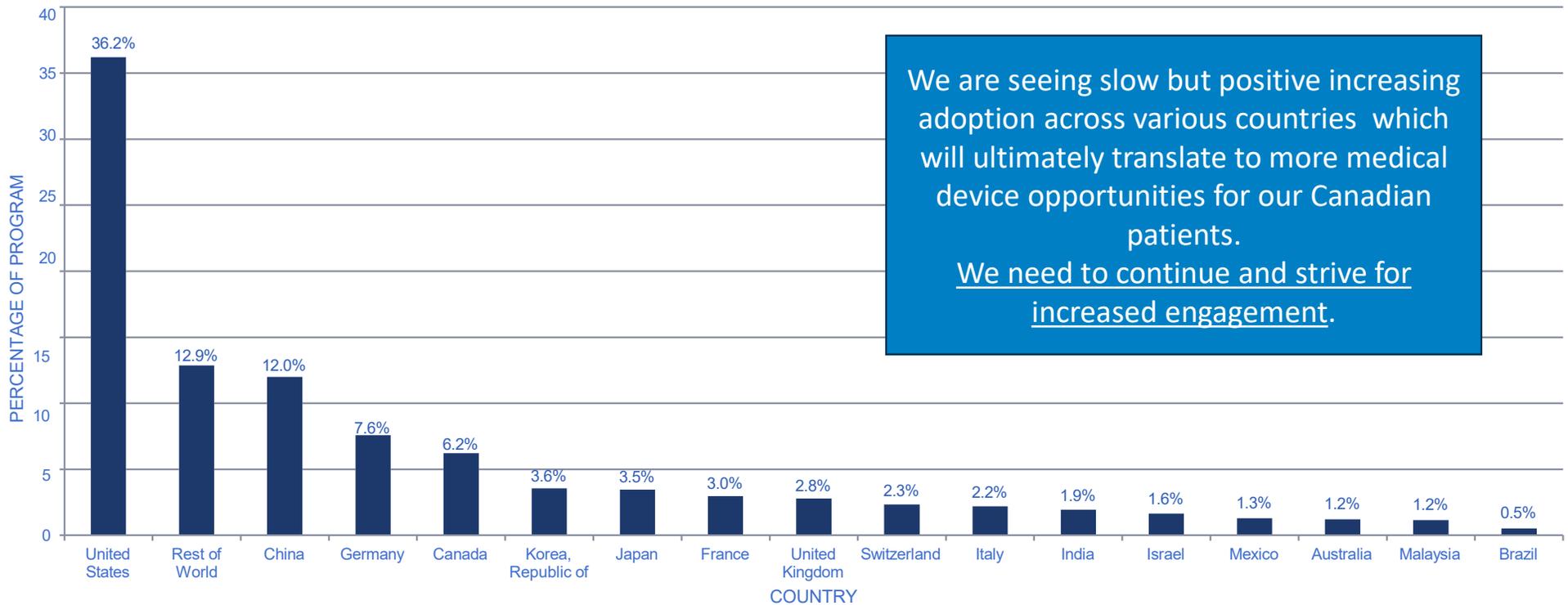
Number of Active Facilities
Participating with MDSAP

4,351

Number of MDSAP
Certificate Holders

MDSAP Sites by Country

Facility Site Location by Country
Top 15 + Regulatory Authorities

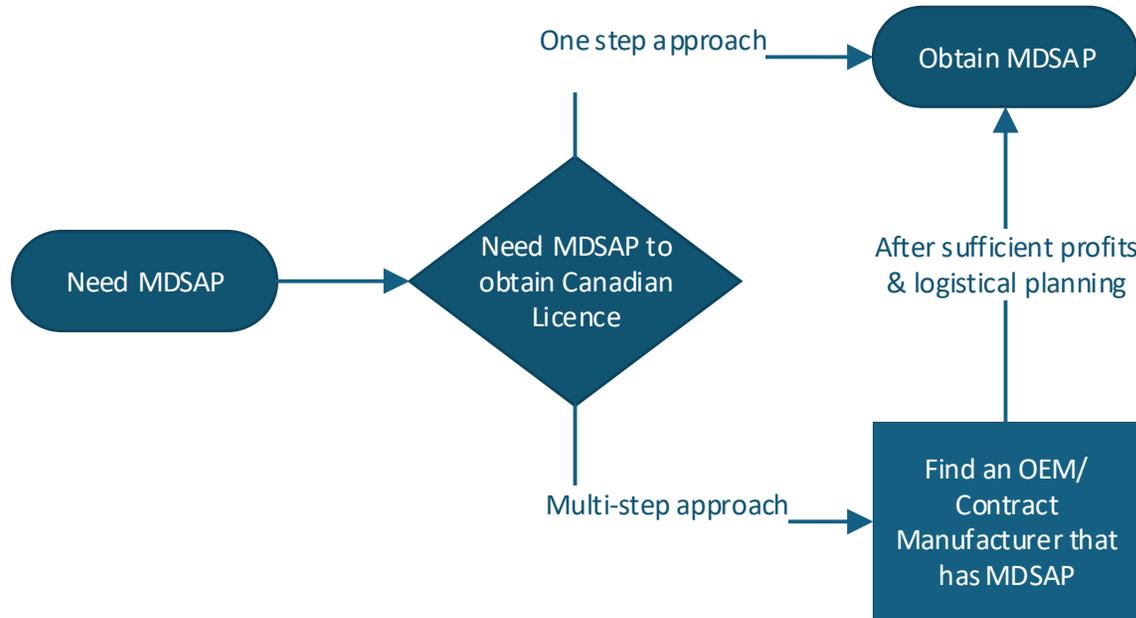


We are seeing slow but positive increasing adoption across various countries which will ultimately translate to more medical device opportunities for our Canadian patients.
We need to continue and strive for increased engagement.

Using MDSAP certification as a strategies for access into the Canadian Market



Pathways to MDSAP and Business Considerations



One-step approach

Pro: higher profit margin, less follow up steps, independence from other companies, control on selected AO and future product line flexibility

Con: Slower to market (initial certification), larger initial investment (financial and personnel)

Multi-step approach

Pro: Quicker to market (initial certification), lower initial investment (financial and personnel)

Con: lower profit margin, additional steps to obtain independent MDSAP, reliance on another company, less flexibility on future product lines

Industry's engagement – Past, Present and future



This Photo by Unkn

The Journey - Industry engagement with Regulators and AOs

1998-2003

Direct engagement with Health Canada



2003-2013

Direct engagement with Auditing Organizations and indirectly with Health Canada



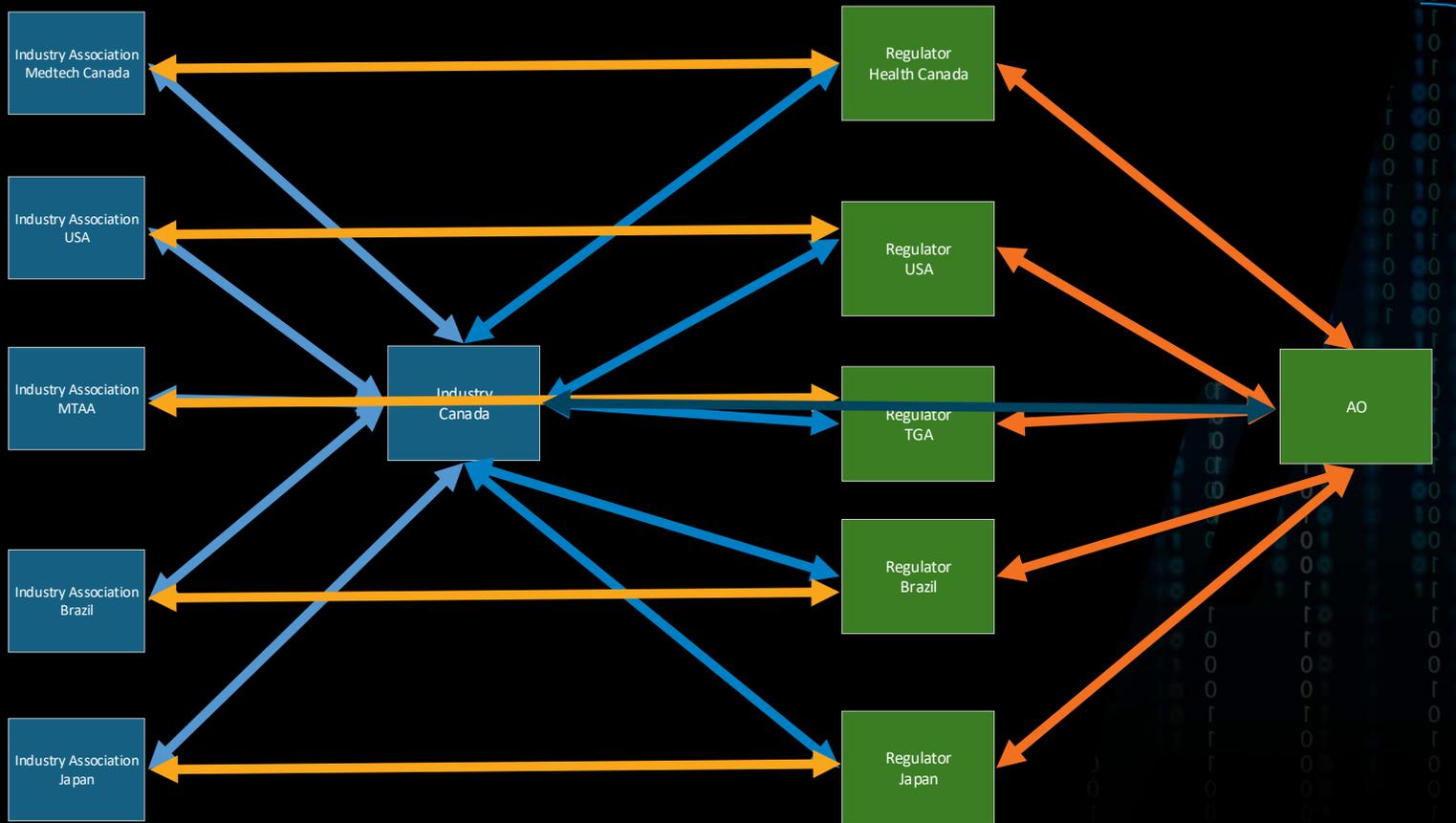
2013-2023

Direct engagement with AO and various regulatory bodies



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MDSAP current mechanisms for feedback – InterNational Company



What is the mechanism to capture within all these streams of communications the necessary data for program enhancement?

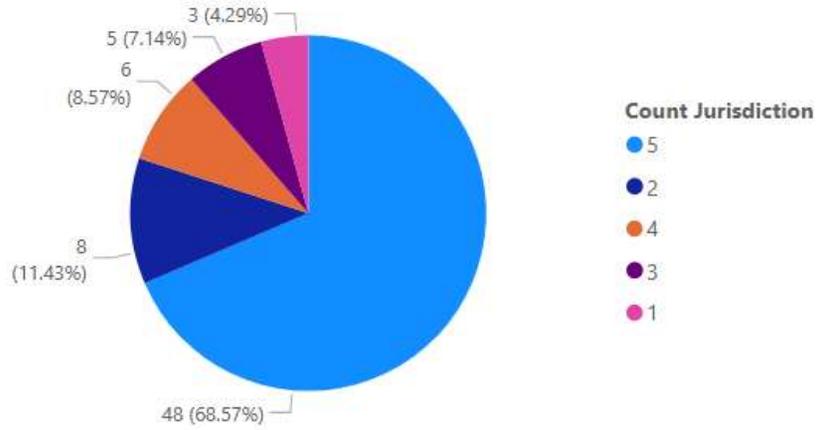
Present state - Industry engagement with Regulators and AOs

- Working to create clear and simple pathways for communication
 - Industry Survey and feedback highlighting areas of improvement that will promote additional industry engagement
 - MDSAP Forum Industry partial engagement (open sessions only)
 - Indirect engagement through our jurisdictions

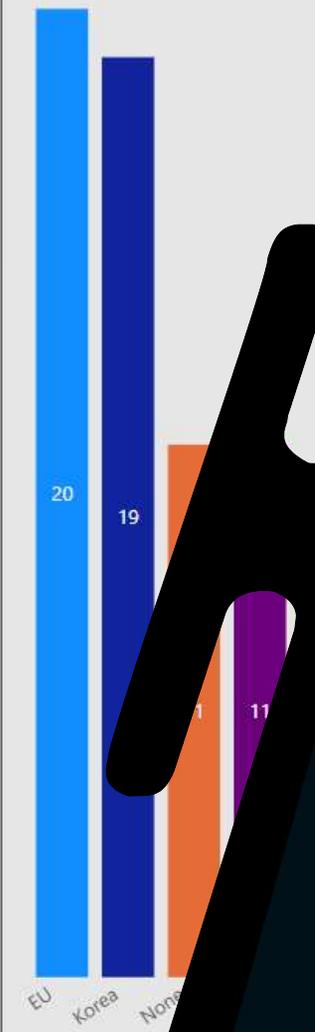


Brazil	Canada	Japan	USA	Australia
56	64	53	67	58

Qty of Jurisdictions on an MDSAP Certificate



Future Jurisd

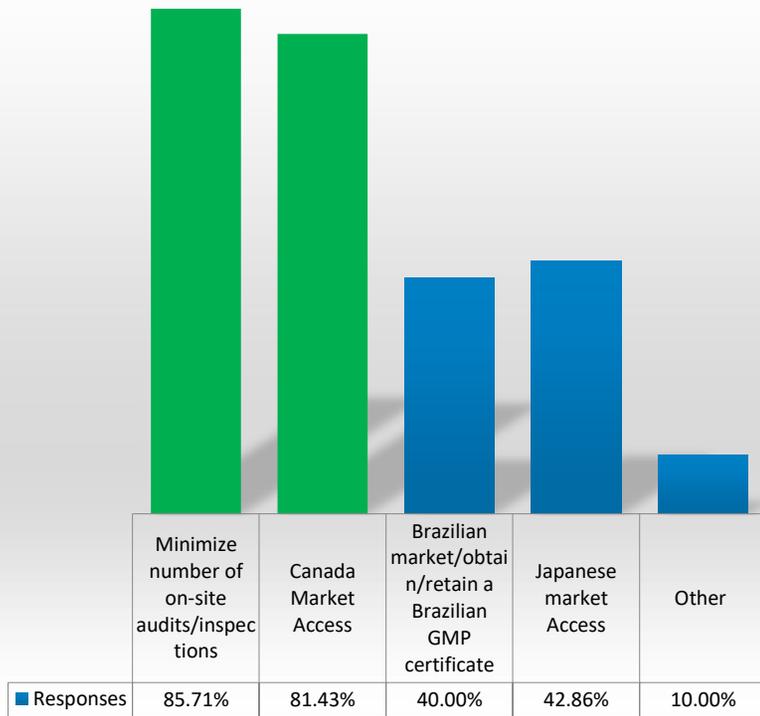


Survey conducted in 2024

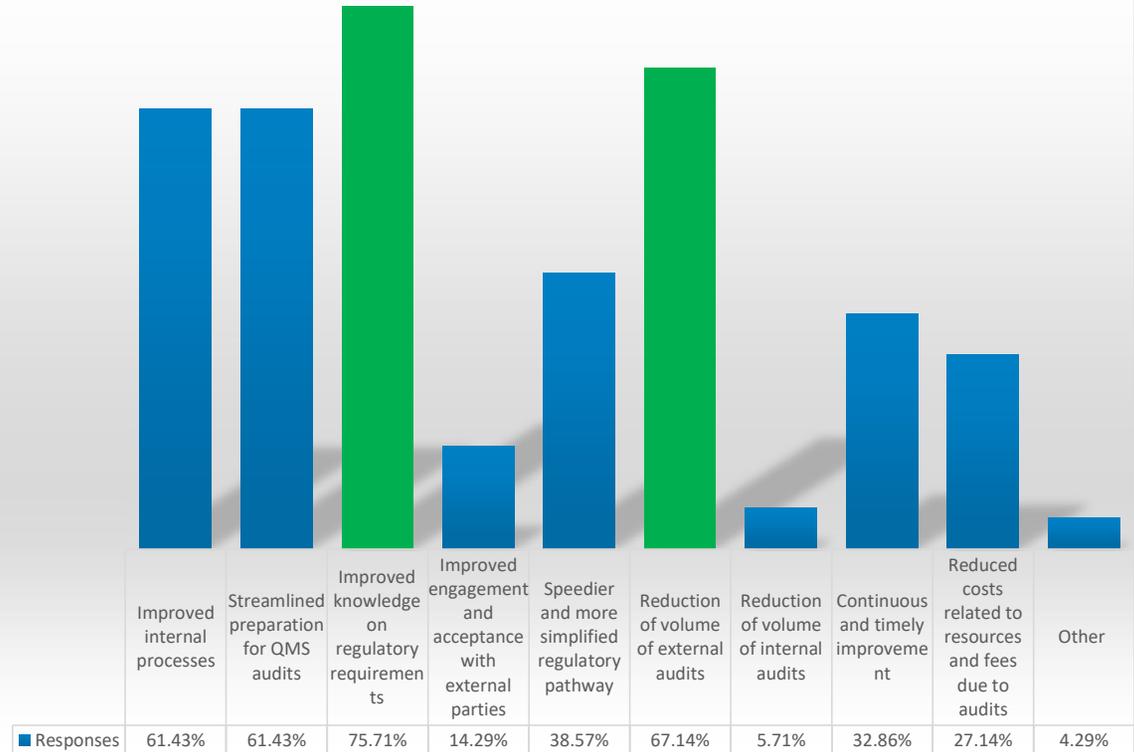
- Provided Great insights into benefits and areas where industry seeks improvement.

Information and Benefits

Reason for participation in MDSAP

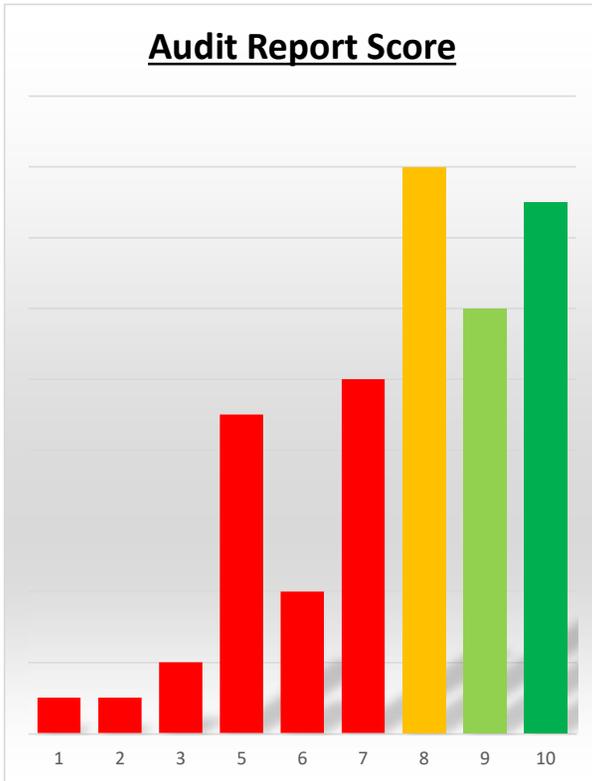


Benefits of MDSAP



Industry Challenges – couple of key areas

Audit Report Score



Auditor Regulatory Expertise



Additional recommended areas

Canada:

- MDSAP certificate scope
- MDSAP Issue date vs effective date

General

- Audit costs (Small and Medium Enterprises in particular)
- SME audit day reduction is a confusing program and is not being offered / applied accurately.
- Audit Length (alignment across AOs)
- Audit Experience (Virtual / Hybrid / In person)
- MDSAP PR (training of industry at large to understand the benefits of MDSAP)
- Expanding and explaining MDSAP Financial benefits to companies – bridging the gap between Quality and Finance.

The Future...

- MDSAP IG – direct and ongoing engagement between Industry / MDSAP RAC and AOs
- Voice of the observers and Affiliate associations – TBD
- Increased collaboration of Industry with AOs – via the AO committee and individually (eg this working group)
- Data-driven voice of industry (Canada and future Joint association surveys that capture other jurisdictions)
- Work done by Medtech Canada in addition:
 - WG - Canada MDSAP Survey
 - WG – MDSAP SMEs (Capture Small and Medium Enterprises that have and have not engaged in MDSAP and seeking their unique perspective on challenges for adoption)
 - Ongoing Bilat with Health Canada
 - Medtech Canada Conference ongoing Panel discussion (April 23-24, 2026)



New Canada MDSAP Survey!

Intended target audience:

- Not based on where the manufacturing is taking place but on the jurisdictional scope of the certificate.
- Majority of the current 4,351 Certificate holders already have Canada within the scope (91% or more based on last survey).

Survey logistics:

- Auto-saving
- 20-40 minutes to complete
- Comprehensive
- Anonymous*

What will Medtech Canada do with the data?

- Create comprehensive and data-driven dashboard
- Track trends and signals
- Communicate with Health Canada, AOs and Industry on areas of improvement as well as positive trends
- Support the collaborative joint-association MDSAP IG voice to ultimately drive continuous improvement and voice of industry to the MDSAP RAC and program enhancement.

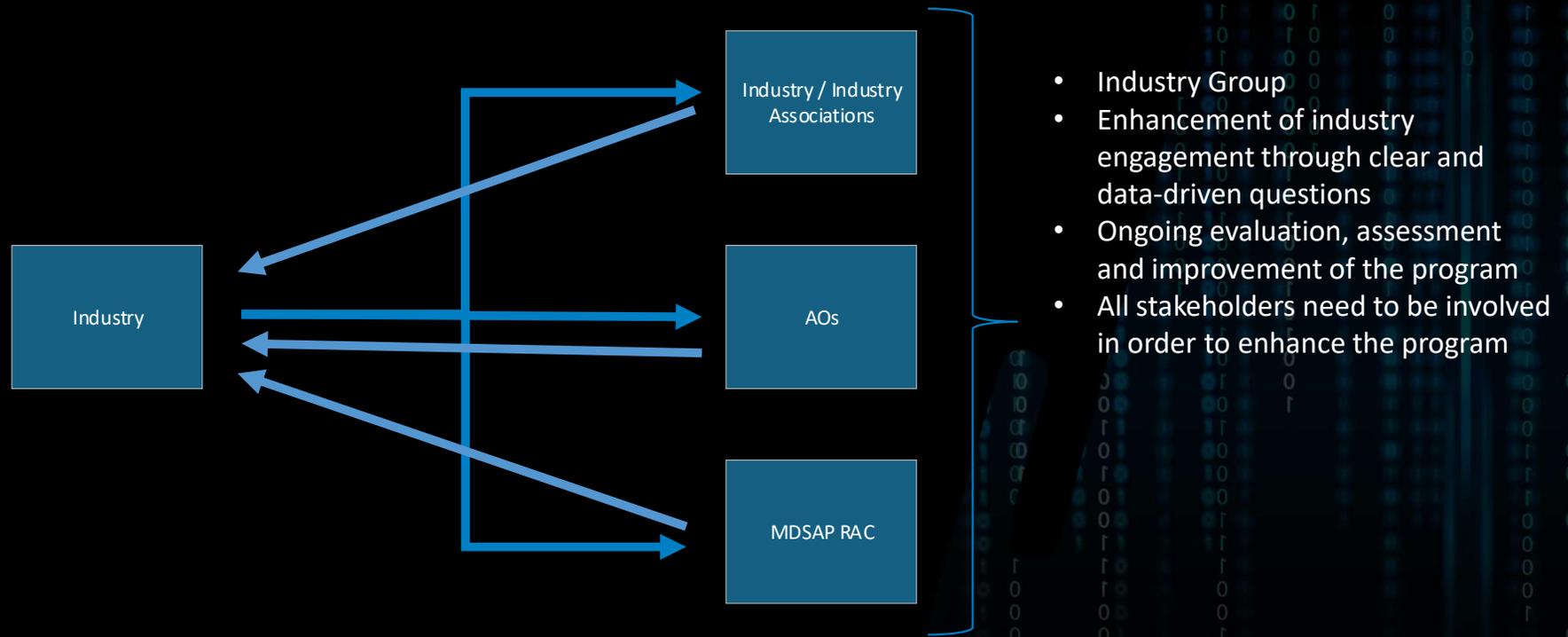


<https://www.surveymonkey.com/r/353C3M9>

* Responder can choose to remain anonymous or provide contact information in order to receive survey updates

Recommended MDSAP Industry mechanism of feedback

Industry-led Survey



* Existing direct communication to regulators on Country-specific areas of enhancement will be separate using current country-specific mechanisms

Conclusion

- Since its launch, the Medical Device Single Audit Program (MDSAP) significantly reshaped the regulatory environment for medical devices both in Canada and internationally, with over 31,000 audits in 82 countries and 7,300+ active facilities.
- Its success relies on collaboration among industry, Auditing Organizations, and Regulators. As Canada's medtech sector grows, maintaining a strong industry voice is vital to support innovation, safety, and patient care.
- Medtech Canada and partners are committed to advancing MDSAP through open dialogue, data-driven feedback, and continuous improvement.
- The program's future depends on active engagement, transparency, and a shared focus on better health outcomes worldwide.

MDSAP Session – an engaging Topic at our Medtech Canada Conference

SAVE THE DATE

CANADA'S
REGULATORY & QUALITY
MEDTECH CONFERENCE 2026

PRESENTED BY
Medtech
Canada

April 23 -24, 2026
Rogers Centre, Ottawa

[Learn More](#)

More Information :
www.medtechcanada.org

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SCAN ME